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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/745,243

12/21/2000

Narendra Parikh

JBP514

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7590

02/26/2004

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EXAMINER

CHOI, FRANK I

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/745,243

**Applicant(s)**

PARIKH ET AL.

**Examiner**

Frank I Choi

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-14, 16-22 and 24-73 is/are pending in the application.
- 4a) Of the above claim(s) 37-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-14, 16-22, 24-36, 73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>20031126</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/26/2003 has been entered.

#### ***Specification***

The attempt to incorporate subject matter into this application by reference to USP dissolution specifications is improper because an application for a patent when filed may incorporate "essential material" by reference to (1) a U.S. patent, (2) a U.S. patent application publication, or (3) a pending U.S. application, subject to the conditions set forth below.

"Essential material" is defined as that which is necessary to (1) describe the claimed invention, (2) provide an enabling disclosure of the claimed invention, or (3) describe the best mode (35 U.S.C. 112). In any application which is to issue as a U.S. patent, essential material may not be incorporated by reference to (1) patents or applications published by foreign countries or a regional patent office, (2) non-patent publications, (3) a U.S. patent or application which itself incorporates "essential material" by reference, or (4) a foreign application. See MPEP Section 608.01(p)(I). The USP is essential material as is used to describe the invention, provide enabling disclosure of the claimed invention and/or describe the best mode in that claimed invention requires that the composition meet the USP dissolution specification for immediate release dosage forms containing the particular active ingredient.

#### ***Claim Rejections - 35 USC § 112***

Claims 2-14, 16-22, 24-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's claims require that the composition meet the USP dissolution specification for immediate release dosage forms containing the particular active ingredient which renders the claims indefinite as USP standards are subject to change. As such, the scope of the claims is unclear.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-14, 16-22, 24-36, 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2-53271 in view of Friend et al. (US Pat. 6,139,865) and CA 2068366

JP 2-53271 is cited for the same reasons as the prior Office Action and the same is incorporated herein.

Friend et al. disclose the use of ethyl cellulose, cellulose acetate phthalate and/or hydroxypropylmethyl cellulose phthalate and the like for effective taste masking of drugs (Column 7, lines 22-39). It is taught that the microcapsules provide dissolution of at least about 90% at 45 minutes (Column 8, lines 36-66). It is taught that the particle size of the microcapsules will be in the range of a few microns up to about 1000 microns or more, with particle sizes in the approximately 30 microns to 800 microns, and the particles sizes in the range

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of approximately 40 microns to 250 microns particularly preferred and that those skilled in the art will recognize that the components of the microcapsules, the relative quantities of the drug and polymeric coating material, the size of the microcapsules and other parameters, can be easily varied to provide of different degrees of taste masking and various release profiles (Column 8, lines 31-43).

CA 2068366 disclose that ethyl cellulose is a water-insoluble polymer and that cellulose acetate phthalate and hydroxypropylmethyl cellulose phthalate are enteric polymers (Pg. 8, lines 26-33, Pg. 9, lines 30-38).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose examples of enteric and insoluble polymers used in the first coating layer. However, the prior art amply suggests the same as it is known in the art to use water-insoluble and/or enteric polymers, such as ethyl cellulose, cellulose acetate phthalate, cellulose acetate butyrate and/or hydroxypropylmethyl cellulose phthalate and the like for effective taste masking of drugs. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation the use of the above polymers would provide taste masking of the drug.

Examiner has duly considered Applicant's arguments but deems them moot in light of the new grounds of rejection herein. Examiner notes that Applicant has not addressed how the limitations of claim 73 overcome the prior art. A new claim constitutes an amendment, as such, Applicant was required to show how the limitations of claim 73 overcome the prior art. See MPEP 714.02. Notwithstanding the same, as indicated above it is well within the skill of one of ordinary skill in the art to prepare particles having various sizes, as desired, including sizes

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within the claimed range of about 50 to about 500 microns. Although Examiner is not persuaded by Applicant's arguments<sup>1</sup>, Examiner withdraws the 103(a) rejection of claims 1-36 over JP 2-53271 in view of Guley in view of the better art cited above and to avoid cumulative art rejections. See MPEP 706.02 [R-1].

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

### Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached at (571)272-0602. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

February 21, 2004



S. MARK CLARDY  
PATENT EXAMINER  
GROUP 1200  
1616

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<sup>1</sup>The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 208 USPQ 871 (CCPA 1981). Clearly, it is within the skill of one of ordinary skill in the art to employ enteric and insoluble polymers in sustained and immediate release formulations as desired. As such, the fact that Guley discloses sustained release formulations does not require that the formulations of Guley be bodily incorporated into JP 2-53271. Further, the previous examiner clearly elucidated the Guley was being cited for its teachings of the specific polymers.